“Regulatory Aspects of Medical Devices”

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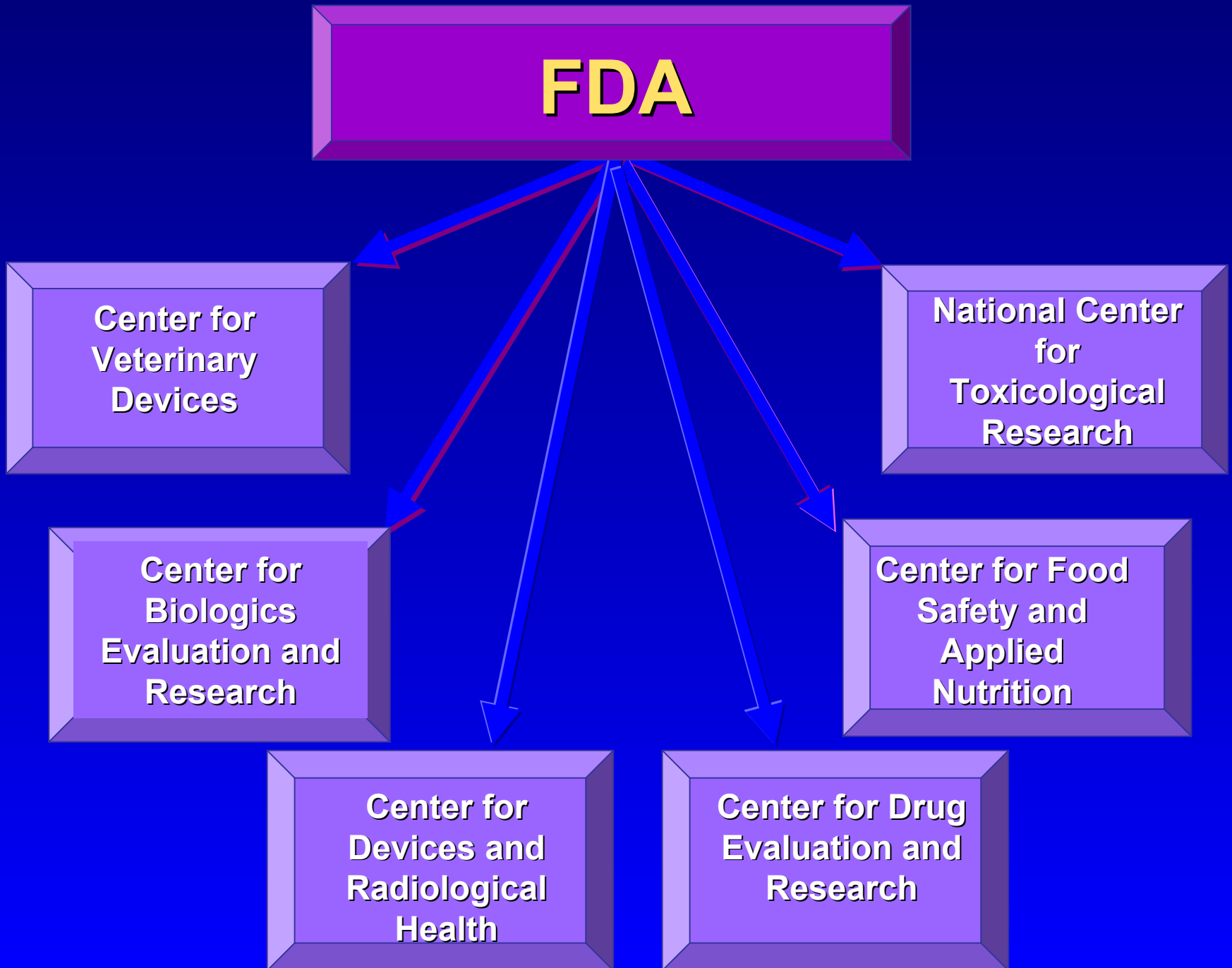
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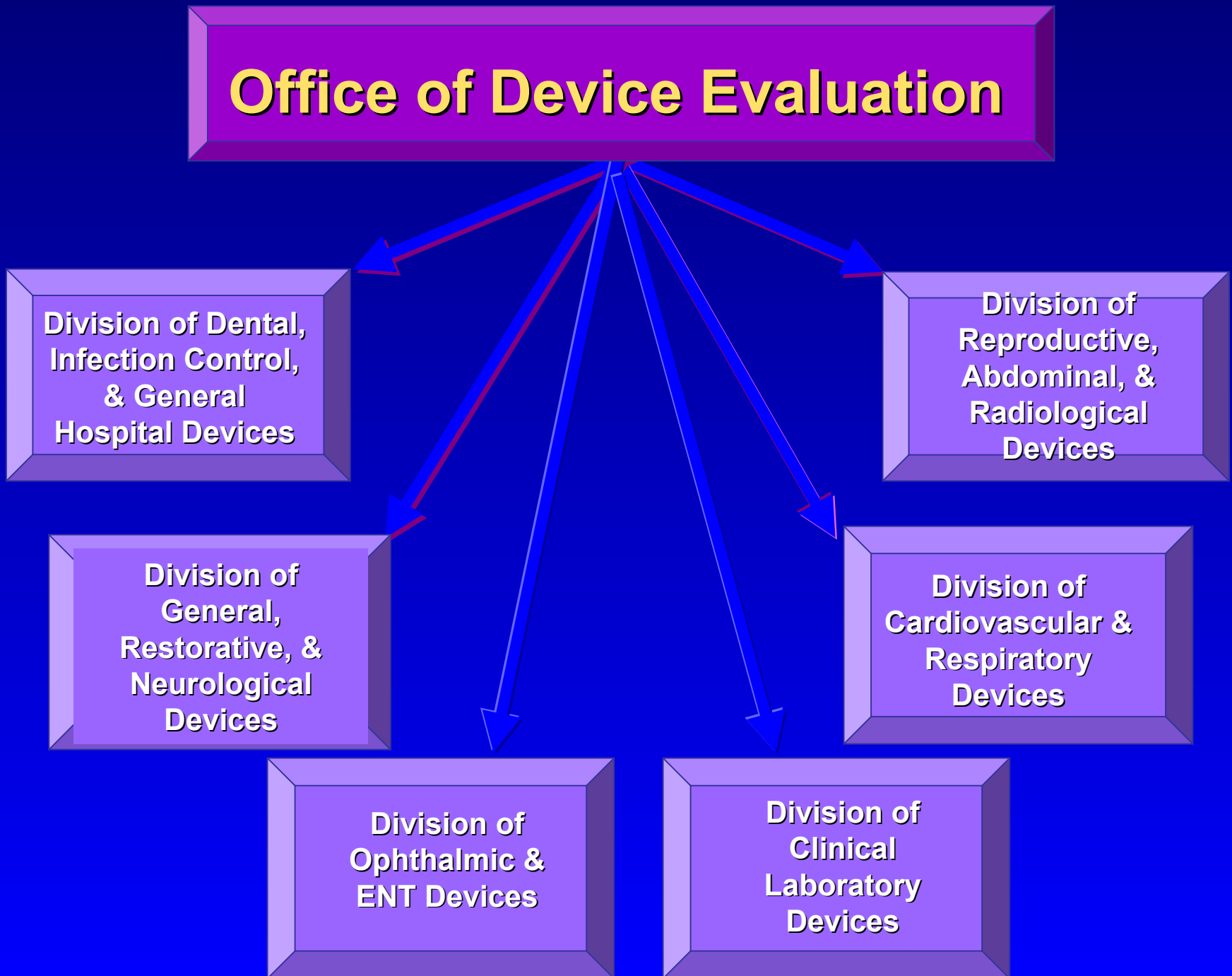
Office of Device Evaluation
Division of Dental, Infection Control, & General Hospital Devices
Division of Reproductive, Abdominal, & Radiological Devices
Division of General, Restorative, & Neurological Devices
Division of Cardiovascular & Respiratory Devices
Division of Ophthalmic & ENT Devices
Division of Clinical Laboratory Devices

Device Combination Products

- Includes device/drug and device/biologic combinations
- For combination products, lead center determined by principle agent
- Examples: interactive wound and burn dressings, infusion pumps, antibiotic bone cement

Device Classification

- Determines level of regulation applied to the device
- Class I
  - General Controls (GMPs)
  - Low risk devices
  - 46% of all devices
- Class II
  - General/Special Controls
  - Moderate risk devices
  - 47% of all devices
- Class III
  - General/Special controls & PMA
  - Moderate and high risk devices
  - Clinical data needed
  - <10% of all devices

Regulatory Pathways

- 510(k) - Premarket Notification
  - Class I/II
- PMA - Premarket Approval
  - Class III
- PDP - Product Development Protocol
  - Class III
- HDE - Humanitarian Device Exemption
  - Class III

Premarket Notification (510(k))

- "Me-too" devices
- Must establish substantial equivalence to predicate device
- If SE, go to market
- If not SE, then Class III
- 90 day review

Premarket Approval (PMA)

- Device must be shown to be have "reasonable assurance of safety and effectiveness"
- Safety -- probable benefits outweigh the probable risks
- Effectiveness - in a significant portion of the target population, provides clinically significant results

Review of PMA

- Team: medical officer, engineer, biologist, statistician, labeling expert, manufacturing expert
- 45 days to file; 180 days to review
- Advisory committee input

Product Development Protocols (PDPs)

- Similar to PMA
  - Establish safety & effectiveness
  - Bench, animal, and human testing
- Different from PMA
  - Approval based on protocol (hypothesis, objectives, endpoints, etc.) before study starts

Humanitarian Device Exemption (HDE)

- Devices for the txt or dx of diseases affecting < than 4,000 pts in US per year
- Device otherwise not available
- No alternative device
- Exemption from effectiveness
- Safety threshold is different

Specifics of an HDE

- IRB approval required
- Informed consent not req'd
- Subject to GMPs
- Cannot make a profit
- 75 day review

ODE Contacts

- 510(k) Staff - (301) 594-1190
- IDE/HDE Staff - (301) 594-1190
- PMA/PDP Staff - (301) 594-2186
- Jurisdictional Issues for Combination Devices
  - Eugene Berk (301) 594-1190
- **Web-sites**
  - Center for Devices and Radiological Health: http://www.fda.gov/cdrh/index.html
  - Device Advice: http://www.fda.gov/cdrh/devadvice/index.html

ODE Contacts continued...

- Division of Dental, Infection Control, & General Hospital Devices - (301) 443-8879
- Division of General, Restorative, & Neurological Devices
  - (301) 594-1184
- Division of Ophthalmic & ENT Devices
  - (301) 594-2205
- Division of Clinical Laboratory Devices
  - (301) 594-3084
- Division of Cardiovascular & Respiratory Devices
  - (301) 443-8320
- Division of Reproductive, Abdominal, & Radiological Devices - (301) 594-5072